

इंटरनेट

मानक

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Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS/ISO 8009 (2004): MECHANICAL CONTRACEPTIVES - REUSABLE
NATURAL AND SILICONE RUBBER CONTRACEPTIVE DIAPHRAGMS -
REQUIREMENTS AND TESTS [MHD 3: Obstetric and Gynaecological
Instruments and Appliances]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

यांत्रिक गर्भनिरोधक — पुनः उपयोग योग्य प्राकृतिक और सिलिकॉन
रबर के गर्भनिरोधक डायफ्राम — अपेक्षाएँ और परीक्षण

Indian Standard

MECHANICAL CONTRACEPTIVES — REUSABLE
NATURAL AND SILICONE RUBBER CONTRACEPTIVE
DIAPHRAGMS — REQUIREMENTS AND TESTS

ICS 11.200

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 10

NATIONAL FOREWORD

The Indian Standard which is identical with ISO 8009 : 2004 'Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Obstetric and Gynaecological Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Diaphragms are medical devices; therefore, they should be produced under a good quality management system. Reference should be made to the IS/ISO 9000 series in conjunction with IS 15579/ISO 13485. The sampling plans and acceptance quality limits (AQLs) given in this Indian Standard are for referee testing. The AQLs represent the maximum tolerable level of defects in the products. As diaphragms are intended for re-use, manufacturers should strive for entirely defect-free product. The manufacturers may devise and apply additional and alternative quality control measures for their use and after production.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 188 Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests	IS 3400 (Part 4) : 1987 Methods for test for vulcanized rubbers: Part 4 Accelerated ageing (<i>second revision</i>)	Technically Equivalent
ISO 463 Geometrical Products Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges	IS 2092 : 1983 Specification for plunger type dial gauges (<i>first revision</i>)	do
ISO 2859-1 : 1999 Sampling procedure for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	IS 2500 (Part 1) : 2000 Sampling procedure for inspection by attributes: Part 1 Sampling schemes indexed by acceptable quality level (AQL) for lot-by-lot inspection (<i>third revision</i>)	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard.

(Continued on third cover)

Indian Standard

MECHANICAL CONTRACEPTIVES — REUSABLE NATURAL AND SILICONE RUBBER CONTRACEPTIVE DIAPHRAGMS — REQUIREMENTS AND TESTS

1 Scope

This International Standard specifies the minimum requirements and test methods to be used for reusable diaphragms made from natural rubber and silicone rubber. These diaphragms are intended for contraceptive use.

This International Standard is not applicable to other vaginal contraceptive barriers, such as those known as cervical caps, vaginal sponges and vaginal sheaths.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 463, *Geometrical Product Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*

ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1 Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

3 Terms and definitions

For the purpose of this document, the terms and definition given in ISO 2859-1 and the following apply

3.1

lot

↙ batch

collection of diaphragms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, common lots of raw materials, common equipment and personnel

NOTE The size of a lot is not specified in this International Standard, but it may be possible for a purchaser to do so as part of a purchasing contract. Depending on the method of manufacture, multiple sizes can be produced in a defined lot/batch. In such cases, traceability can be maintained by using both the lot number and the size

4 Sampling

Sampling and establishment of the sampling plan shall be carried out as described in ISO 2859-1.

NOTE It is necessary to know the lot size in order to derive from ISO 2859-1 the number of samples to be tested. The lot size varies among manufacturers, and is regarded as part of the process and quality controls used by the manufacturer.

5 Classification

Diaphragms shall be classified into the following types:

- a) **Type 1:** Coil-spring diaphragm, also known as a helically wound diaphragm.
- b) **Type 2:** Flat-spring diaphragm, also known as a flat-leaf diaphragm, watch-spring diaphragm or *Mensinga* diaphragm.
- c) **Type 3:** Arcing-spring diaphragm, also known as an arcing-bend diaphragm or bow-bend diaphragm.

6 Materials

The diaphragm, excluding the spring, shall be made of a natural or silicone rubber compound.

When tested in accordance with ISO 10993-5, the diaphragm material and any lubricant, dressing material or powder applied or recommended by the manufacturer shall not be cytotoxic. Spermicides applied at the time of use are excepted from this requirement.

When tested in accordance with ISO 10993-10, the diaphragm and any lubricant, dressing material or powder applied to it or recommended by the manufacturer shall not cause irritation or sensitization. Spermicides applied at the time of use are excepted from this requirement, but manufacturers shall take steps to recommend spermicides that minimize irritant effects.

The tests stipulated in ISO 10993-5 and ISO 10993-10 are type tests.

7 Design

7.1 General

The diaphragm shall consist of a dome and an integral peripheral rim. The dome of the diaphragm and the portion forming the rim shall be one continuous film.

7.2 Rim

The rim of the diaphragm shall be reinforced with a spring, which shall be sufficiently rigid to hold the rim in a flat, circular configuration.

7.3 Reinforcing spring

The reinforcing spring shall be completely encapsulated and centrally located within the rim.

7.4 Spring ends

The ends of the spring shall be joined in such a manner that the joint does not project through the surface of the rim.

7.5 Dome and rim

The dome and rim shall have a uniform, smooth and non-tacky finish

8 Dimensions

8.1 Diameter

The nominal diameters of preferred sizes shall be 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, 80 mm, 85 mm, 90 mm, 95 mm and 100 mm.

When tested in accordance with Annex A, the two diameter measurements shall not differ by more than 4 % of the nominal size. The mean of these two measurements, called diaphragm diameter, shall equal the nominal size within a tolerance of ± 2 mm.

Examine 13 diaphragms of each size. No diaphragm diameter shall fall outside the limits.

8.2 Dome thickness

When tested in accordance with Annex B, the thickness of the diaphragm dome at the thinnest point measured shall not be less than 0,20 mm.

9 Tensile properties of the dome

9.1 Tensile strength

When tested in accordance with Annex C, the median tensile strength of 13 diaphragms of each size shall not be less than the values given in Table 1.

When tested in accordance with Annex D, the median tensile strength of 13 oven-treated diaphragms of each size shall not be less than the values given in Table 1.

9.2 Elongation at break

When tested in accordance with Annex C, the median elongation at break of 13 untreated diaphragms of each size shall not be less than the values given in Table 1.

When tested in accordance with Annex D, the median elongation at break of 13 oven-treated diaphragms of each size shall not be less than the values given in Table 1.

Table 1 — Minimum median tensile properties

Property	Natural rubber untreated	Natural rubber oven-treated	Silicone rubber untreated	Silicone rubber oven-treated
Tensile strength, MPa	15	11	7	7
Elongation at break, %	650	500	350	350

10 Mechanical properties of rim and spring — Type 1 and Type 2 diaphragms

10.1 Compression resistance

When 13 diaphragms are tested in accordance with Annex E, during the first and 1 000th compressions the distance between the load points, i.e. resulting from compression, of each diaphragm shall not be lower than 55 % and not greater than 85 % of the original diameter.

After the 1 000th compression, the diameter along the axis of compression shall be at least 90 % of the value measured before the test.

After the 1 000th compression, the rubber film shall show no signs of deterioration when examined by normal or corrected vision.

The degree of twist after 1 000 compressions, measured in accordance with Annex F, shall be not more than 20°.

Manufacturers of diaphragms who are certified to the ISO 9000 quality management system or equivalent, and whose suppliers are similarly certified, may use the repeated compression testing part of this method as a type test. In that case, lot-by-lot testing shall consist of a single compression, and measurement of the compression resistance.

10.2 Twisting during compression

When tested in accordance with Annex F, the diaphragm shall not show an angle of twist greater than 20°.

Each lot shall be sampled in accordance with ISO 2859-1:1999, General Inspection Level I, but at least according to code letter K.

When tested in accordance with Annex F, the compliance level shall be an AQL of 1,0 %.

11 Freedom from visible defects

When inspected in accordance with Annex G, the diaphragm shall not show any visible defects.

Each lot shall be sampled in accordance with ISO 2859-1:1999, General Inspection Level I, but at least according to code letter K.

The compliance level shall be an AQL of 0,4 % for the following major defects:

- a) hole in the dome;
- b) exposed spring;
- c) broken spring;
- d) distorted shape;
- e) illegible marking on the diaphragm; and
- f) illegible labelling.

For minor defects, when tested in accordance with Annex G, the compliance level shall be an AQL of 1,0 %.

12 Test report

Test reports shall contain at least the information as described in Annex H.

13 Packaging, labelling and storage

13.1 Packaging

13.1.1 Individual container

Each diaphragm shall be individually packaged in a container designed to protect it from contamination, exposure to light and mechanical damage during normal handling, transport and storage.

13.1.2 Outer container(s)

A convenient number of individual containers shall be packed in one or more outer containers which shall be sufficiently robust to protect the contents during transport and storage.

The individual container shall be reusable so that it can be used to protect the diaphragm for the term of its useful life.

13.2 Labelling

13.2.1 Diaphragm identification

Each diaphragm shall be legibly marked with the following information:

- a) the manufacturer's name or recognized trademark; and
- b) the nominal size, in millimetres.

13.2.2 Individual container identification

The container, as received by the user, shall be legibly marked with the following information:

- a) the manufacturer's and/or distributor's name or recognized trademark;
- b) the manufacturer's lot number;
- c) the nominal size, in millimetres;
- d) the manufacturer's recommended last date for supply to the consumer (month and year), i.e. the date after which the diaphragm should not be distributed to consumers. This date shall be no more than two years from the date of manufacture, unless justified by real-time or accelerated test data; and
- e) the material of which the diaphragm is made.

13.2.3 Instructions

Each individual container shall contain instructions for the use and care of the diaphragm in accordance with Annex I.

13.3 Storage

Rubber tends to deteriorate with age. Diaphragms are packed in a way which normally protects them during storage. Nevertheless, they should not be kept in stock longer than necessary, especially in warm climates. They should be stored in a cool, dry place and should be kept in containers such that the contents will not be subject to mechanical damage or light. As soon as any diaphragm shows deterioration (e.g. tackiness, brittleness, crazing) of the rubber, it should be destroyed.

The diaphragm should not be allowed to come into contact with oil-based antiseptic phenols and their derivatives, petroleum-based grease, petroleum spirit, kerosene and other related organic products.

Normally it is recommended to destroy test diaphragms after tests are completed. Sometimes diaphragms need to be kept to demonstrate particular problems, thus it is important that these diaphragms be marked or stored in such a way that unintentional use is prevented.

Annex A (normative)

Determination of size

A.1 Scope

This annex specifies a method for determining the size of reusable natural rubber and silicone rubber contraceptive diaphragms.

A.2 Principle

Size is determined by measurement of the external diameter of the diaphragm

A.3 Apparatus

A.3.1 Measuring device, with a scale graduated in millimetres.

A.4 Procedure

A.4.1 The diaphragm shall not be compressed or distorted during the measurement

A.4.2 Visually inspect the diaphragm. If it does not appear circular, identify by eye the minimum diameter, and when measuring in accordance with A.4.3 take one of the measurements on that axis

A.4.3 Place the diaphragm on the measuring device (A.3.1). Measure, to the nearest millimetre, the external diameter of the rim at two positions at right angles to one another. Calculate the mean value to the nearest millimetre.

A.5 Expression of results

The test report shall include elements specified in Annex H and the actual size values measured for each diaphragm, the difference between them, and the calculated mean value of the external diameter of the rim, expressed in millimetres.

Annex B **(normative)**

Determination of dome thickness

B.1 Scope

This annex specifies a method for determining the dome thickness of reusable natural rubber and silicone rubber contraceptive diaphragms.

B.2 Principle

The dome thickness is measured by means of a specified dial gauge.

B.3 Apparatus

B.3.1 Dial gauge, graduated in divisions of not more than 0,01 mm and in accordance with ISO 463.

The gauge shall be firmly held in a rigid stand over a flat baseplate. The dial gauge shall be fitted with a flat contact of diameter between 3 mm and 7 mm, perpendicular to the plunger and parallel to the baseplate, and

Annex C **(normative)**

Determination of tensile properties

C.1 Scope

This annex specifies a method for determining the tensile properties of the dome of reusable natural rubber and silicone rubber contraceptive diaphragms.

C.2 Principle

A test piece is cut from the dome of a diaphragm and stretched until it breaks. The tensile force and elongation at break are measured.

C.6 Calculation of results

C.6.1 The tensile strength, σ , expressed in megapascals, of each test piece shall be calculated using the following equation:

$$\sigma = \frac{F}{2wt}$$

where

F is the breaking force, in newtons;

w is the width of the test piece (i.e. 2 mm);

t is the thickness of the test piece, in millimetres.

The result shall be rounded to the nearest megapascal.

C.6.2 The elongation at break, E , expressed as a percentage, of each test piece shall be calculated using the following equation:

$$E = \frac{2l + C_{\text{roll}} - C_{\text{int}}}{C_{\text{int}}} \times 100$$

where

l is the final distance between the centres of the rollers, in millimetres;

C_{roll} is the circumference of the roller, in millimetres;

C_{int} is the internal circumference of the ring (i.e. 100 mm).

The result shall be rounded to the nearest 10 %.

C.7 Expression of results

The test report shall include elements from Annex H, and the tensile strength and elongation at break of each test piece.

Annex D **(normative)**

Determination of deterioration after accelerated ageing by oven treatment

D.1 Scope

This annex specifies a method for determining the resistance to deterioration of reusable natural rubber and silicone rubber contraceptive diaphragms.

D.2 Principle

Test pieces are conditioned at an elevated temperature for a specified time and examined for deterioration, followed by measurement of the tensile strength and elongation at break in accordance with Annex C.

D.3 Apparatus

D.3.1 Oven, as specified in ISO 188.

D.3.2 Die, for cutting rings having an internal circumference of $(100 \pm 0,5)$ mm and a radial width of $(2 \pm 0,02)$ mm.

D.3.3 Dial gauge, as specified in Annex B.

D.3.4 Tensile testing machine, capable of an essentially constant rate of traverse and complying with the following requirements:

- able to apply a force ranging from 0 N to 50 N;
- having two roller test-specimen holders; the diameters of the rollers should be approximately 15 mm; and
- having a roller separation speed of $(8,5 \pm 0,8)$ mm/s or (500 ± 50) mm/min.

D.4 Preparation of test pieces

D.4.1 From the dome of each diaphragm to be tested, cut a ring-shaped test piece using the cutting die (D.3.2).

D.4.2 The test piece shall be obtained by cutting with one stroke of the press. Only test pieces which have been completely separated at the first attempt shall be used.

D.5 Procedure

D.5.1 Condition the test pieces (D.4) in the oven (D.3.1) at $(70 \pm 2)^{\circ}\text{C}$ for (168 ± 2) h

D.5.2 After heating, maintain the test pieces at ambient temperature for at least 16 h but not more than 96 h

D.5.3 Examine the test pieces for tackiness, brittleness and other signs of deterioration with normal or corrected vision and by tactile sensory evaluation.

D.5.4 Measure and calculate the tensile strength and elongation at break in accordance with Annex C.

D.6 Expression of results

The test report shall include elements from Annex H and the following particulars:

- a) description of any deterioration after conditioning;
- b) tensile strength and elongation at break of each test piece.

Annex E (normative)

Determination of compression and fatigue resistances of coil-spring and flat-spring diaphragms

E.1 Scope

This annex specifies a method for determining the compression and fatigue resistances of coil-spring and flat-spring reusable natural rubber and silicone rubber contraceptive diaphragms.

This method is not applicable to diaphragms with springs designed to form an arc when compressed.

E.2 Principle

E.2.1 The springs on samples of diaphragms are first compressed by applying a weight. The requirements limit the deformation caused by the compression.

E.2.2 Following the compression-resistance measurement, the diaphragms are repeatedly compressed to 25 % of their original diameter and released.

E.2.3 After the 1 000th compression, the compression-resistance measurement is repeated. In addition, the permanent set and twist caused by the cyclic deformation are measured.

E.2.4 Manufacturers certified to the ISO 9000 series or equivalent, who purchase springs from a similarly certified supplier, may omit steps E 4 5 to E 4 4 9 on a lot-by-lot testing and use the complete test as a type test.

E.3 Apparatus

E.3.1 Compression testing apparatus, capable of applying to the diaphragm the gravitational force of a mass of 280 g.

An example of a suitable apparatus is shown in Figure E 1.

E.3.2 Device, capable of cyclically compressing one or more diaphragms to (25 ± 5) % of their original diameters.

E.3.3 Twist measuring device, in accordance with Annex F.

E.4 Procedure

E.4.1 Measure the original diameter (D_0) of the diaphragm in accordance with Annex A.

E.4.2 Place the diaphragm between the two metal rods, as shown in Figure E 1.

E.4.3 Release the upper rod slowly so that the diaphragm is compressed across its diameter.

E.4.4 Record the distance, in millimetres, between the load points of the rim after compression for 15 s.

If the diameter D_0 of any one diaphragm does not comply with the requirements of this International Standard then the test of that diaphragm may be discontinued, and it may be considered not to conform.

E.4.5 Mount the diaphragm in the cyclic compression device. The compression device may be used to test one or more diaphragms simultaneously.

E.4.6 Compress the diaphragm 1 000 times in a range of 30 cycles/min to 40 cycles/min, and remove it from the device.

E.4.7 Repeat the compression resistance test as described in E.4.1 to E.4.4.

E.4.8 Measure the diameter of the diaphragm along the axis of compression, using the same apparatus as in Annex A.

E.4.9 Measure the degree of twist in accordance with Annex F.

E.4.10 Examine the rubber film using normal or corrected vision for any sign of deterioration.

E.5 Calculation of results

E.5.1 Before the 1 000th compression, the percentage change in diameter, ΔD shall be calculated using the following equation:

$$\Delta D = \frac{100 \times l}{D_0}$$

where

D_0 is the original diameter, in millimetres;

l is the distance, in millimetres, between load points.

E.5.2 After 1 000 compressions, the percentage change in diameter, ΔD_{1000} shall be calculated from the following equation:

$$\Delta D_{1000} = \frac{100 \times l}{D_0}$$

where

D_0 is the original diameter, in millimetres;

l is the distance, in millimetres, between load points after 1 000 compressions.

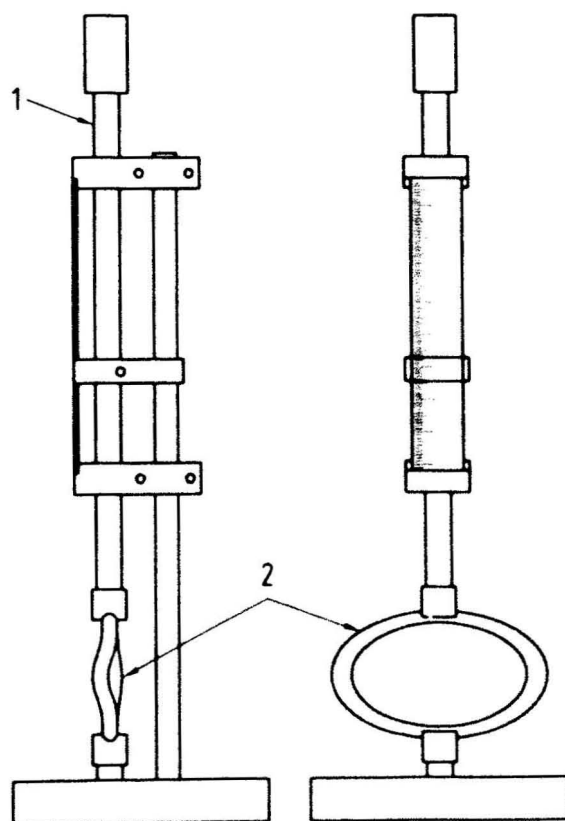
E.5.3 Calculate also the percentage change in compressed diameter ΔD_c from the following equation:

$$\Delta D_c = 100 \frac{D_{1000}}{D_0}$$

E.6 Expression of results

E.6.1 The test report shall include elements from Annex H and the following particulars

- percentage change in diameter (ΔD_0) during the first compression, expressed as a percentage of the original diameter, for each tested diaphragm;
- percentage change in diameter (ΔD_{1000}) after the 1 000th compression, expressed as a percentage of the original diameter, for each tested diaphragm;
- the percentage change in compressed diameter (ΔD_c); and
- any signs of deterioration noted on visual inspection.



Key

- 1 rod, of mass 290 g
- 2 diaphragm

Figure E.1 — Compression testing apparatus

Annex F **(normative)**

Determination of twisting during compression of coil-spring and flat spring diaphragms

F.1 Scope

This annex specifies a method for determining twisting during compression of coil-spring and flat-spring reusable natural rubber and silicone rubber contraceptive diaphragms.

This method is not applicable to diaphragms with springs designed to form an arc when compressed.

F.2 Principle

The rim of the diaphragm is compressed across the diameter of the diaphragm using a suitable apparatus, and the deviation of the rim from the horizontal plane is determined.

F.3 Apparatus

F.3.1 Diaphragm-twist tester, having the features shown in Figure F 1 and comprising two metal rods, one of which is movable along its axis but cannot rotate, and the other which is not movable along its axis but can rotate freely

F.4 Procedure

F.4.1 Mount the diaphragm as shown in Figure F 2 a).

F.4.2 Compress the diaphragm by adjusting rod A so that the distance, l , between the ends of the rods is in accordance with Table F 1 [see Figure F 2 b)]

F.4.3 Measure the angular rotation of rod B as indicated by the pointer P [see Figure F 2 c)]

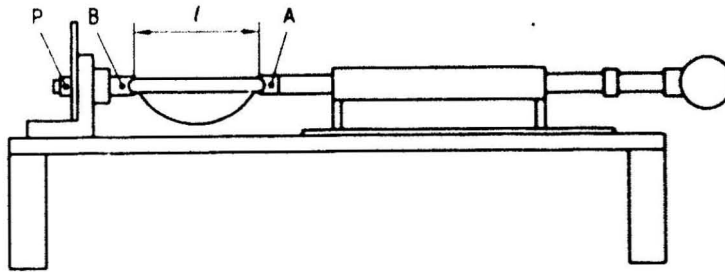
F.5 Expression of results

The test report shall include elements from Annex H, the angular deviation for each diaphragm and the number of diaphragms that show a value of twist greater than 20° .

Table F.1 — Distance between rods for preferred sizes of diaphragms

Nominal size of diaphragm	Distance between rods ^a <i>l</i> mm
55	21.5
60	22.5
65	23.5
70	24.5
75	25.5
80	26.5
85	27.5
90	28.5
95	29.5
100	30.5

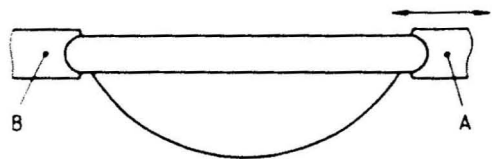
^a The distance for non-preferred sizes should be determined by interpolation or extrapolation



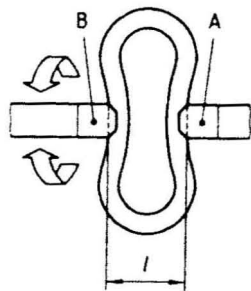
Key

- A non-rotating rod
- B rotating rod
- P pointer

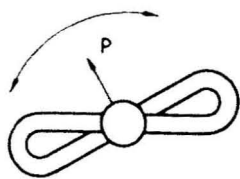
Figure F.1 — Diaphragm-twist tester



a) Mounting the diaphragm



b) Adjusting distance l



c) Measuring angular rotation

- Key**
- A non-rotating rod
 - B rotating rod
 - P pointer

Figure F.2 — Mounting and twisting diaphragms

Annex G **(normative)**

Determination of visible defects

G.1 Scope

This annex specifies two alternative methods for determining visible defects in reusable natural rubber and silicone rubber contraceptive diaphragms, viz. inspection over a lamp and inspection by inflation. The methods in G.3 and G.4 are of equal validity.

G.2 Principle

Visual inspection of the rim and the distended dome of the diaphragm is carried out

G.3 Inspection over a lamp

G.3.1 Apparatus

G.3.1.1 Glass cylinder with a light source inside.

The cylinder shall not be heated by the light source to the extent that it affects the rubber in the diaphragm. Figure G.1 illustrates an example of a suitable apparatus.

G.3.2 Procedure

Inspect the rim and then pull the diaphragm over the glass cylinder (G 3.1.1) so that the rubber is distended to approximately twice its normal linear dimensions. Move the diaphragm around and visually inspect for defects in the dome with normal or corrected vision.

G.4 Inspection by inflation

G.4.1 Apparatus

G.4.1.1 Device to hold the rim of the diaphragm correctly and maintain the dome in a distended state by air inflation.

Figure G.2 illustrates an example of a suitable apparatus.

G.4.2 Procedure

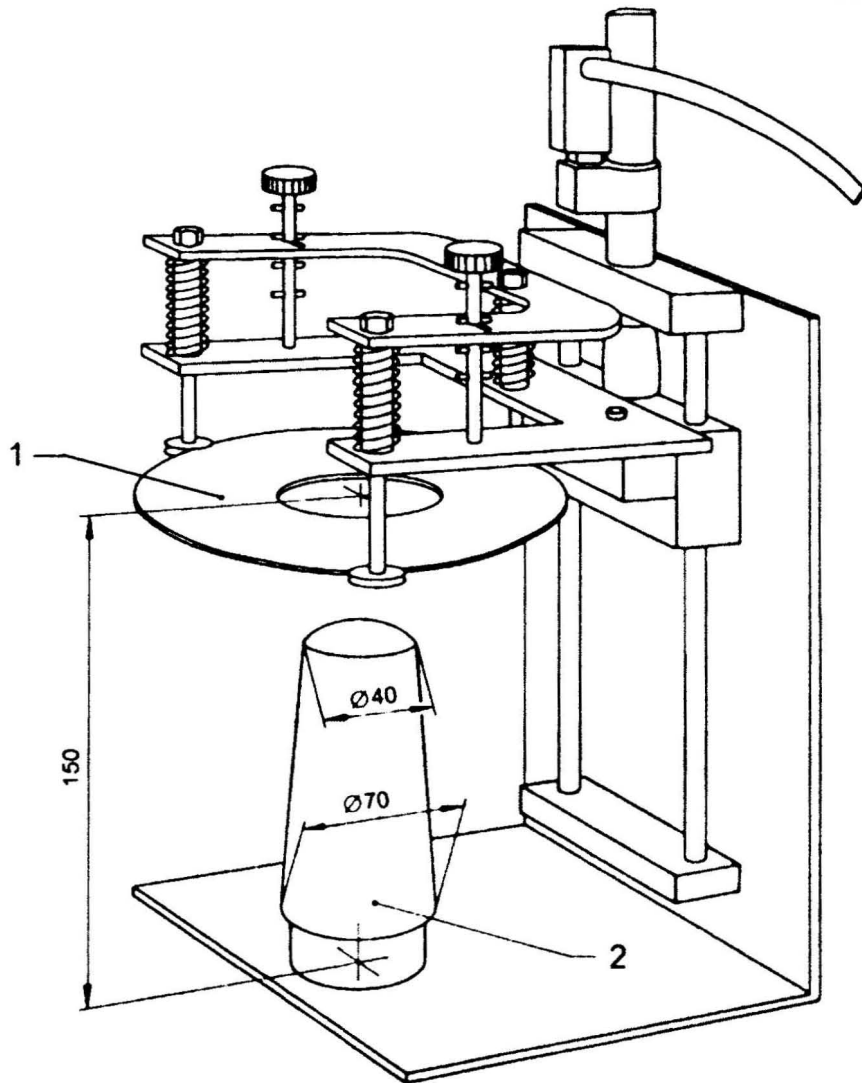
Inspect the rim and then inflate the diaphragm with air, using the apparatus described in G.4.1.1, for 1 min so that the rubber is distended to approximately twice its normal linear dimensions, and visually inspect the inflated diaphragm for defects in the dome with normal or corrected vision.

G.5 Expression of results

The test report shall include elements from Annex H and the following particulars:

- a) the test method used;
- b) number of diaphragms with one or more of the following visible major defects:
 - 1) hole in dome;
 - 2) exposed spring;
 - 3) broken spring;
 - 4) distorted shape;
 - 5) illegible labelling.
- c) number of diaphragms with one or more of the following visible minor defects:
 - 1) thin spots in the dome (including the edges);
 - 2) embedded particles;
 - 3) surface tackiness;
 - 4) any other defects likely to affect the serviceability of the diaphragm.

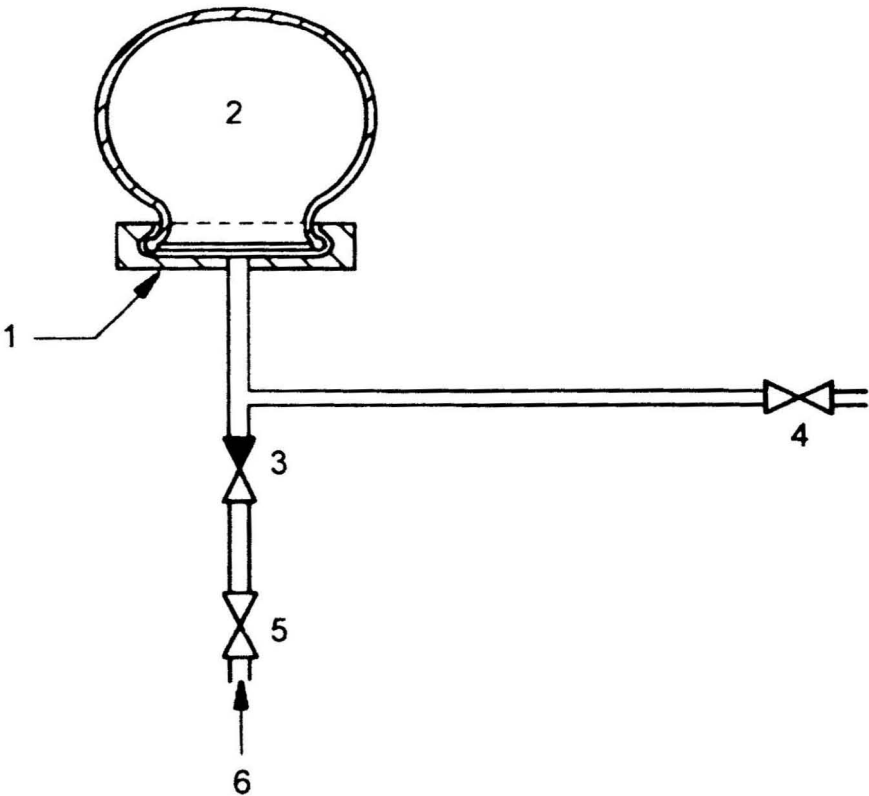
Dimensions in millimetres



Key

- 1 ring for holding diaphragm
- 2 lamp

Figure G.1 — Example of suitable apparatus for inspection over a lamp



- Key**
- 1 clamping ring suitable for the size of the diaphragm
 - 2 expanded diaphragm
 - 3 nonreturn valve
 - 4 air-relief valve
 - 5 valve
 - 6 pressure source

Figure G.2 — Example of a suitable apparatus for inspection by inflation

Annex H (normative)

Test report

The test report shall contain at least the following information:

- a) name and address of the test laboratory;
- b) name and address of the client, if applicable;
- c) identification of the test report;
- d) identification of the test sample (sample size, lot number and lot size) and of the responsible party who has taken the sample;
- e) the origin of the sample and the date of the sample's arrival in the laboratory, if applicable;
- f) a reference to this International Standard and the relevant clauses and annexes;
- g) a description of all deviations from this International Standard;
- h) the results, in accordance with the relevant annexes;
- i) the measurement error, if available;
- j) date of the test report, and the signature and title of the person responsible for the report.

Annex I
(normative)



- e) Because of the deleterious effect of oil and petroleum-based greases, including petroleum jelly, these materials should not be used to lubricate diaphragms made of natural rubber. A lubricant based on water-soluble material or other lubricant having no harmful effect on rubber should be used.
- f) Exposure to light should be kept to a minimum for diaphragms made of natural rubber.
- g) The diaphragm should be stored in its container when not in use.

Bibliography

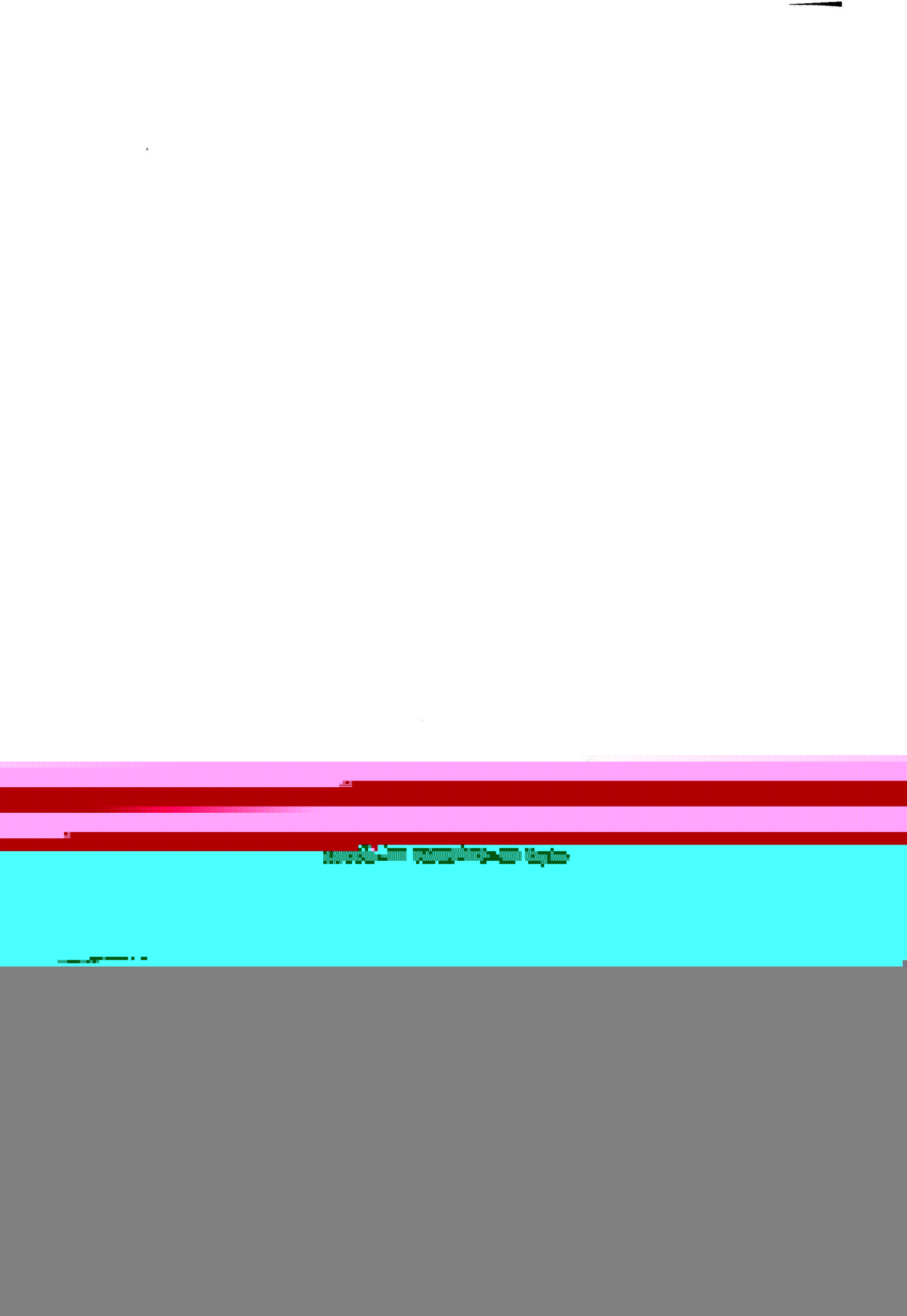
- [1] ISO Guide 7, *Guidelines for drafting of standards suitable for use for conformity assessment*
- [2] ISO 2230, *Rubber products — Guidelines for storage*
- [3] ISO 9000, *Quality management systems — Fundamentals and vocabulary*
- [4] ISO 9001, *Quality management systems — Requirements*
- [5] ISO 9004, *Quality management systems — Guidelines for performance improvements*
- [6] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*
- [7] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*
- [8] ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*
- [9] ISO 14971, *Medical devices — Application of risk management to medical devices*

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.



(Continued from second cover)

International Standard	Title
ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity

BIS Certification Marking clause is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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